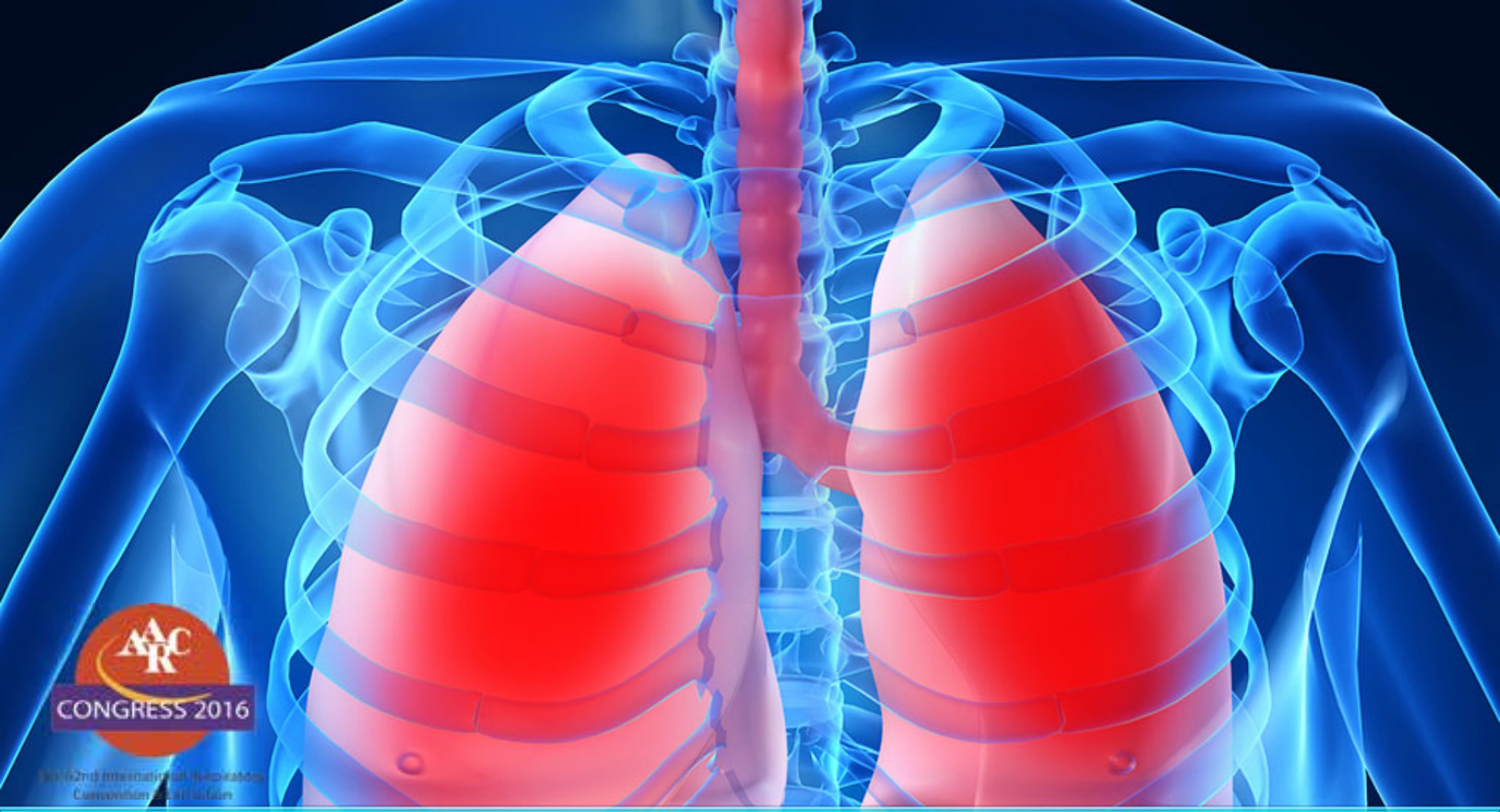

Automated Subglottic Aspiration Systems in Reduction of VAP

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Conflict of Interest

This research is sponsored by FloSure Technologies and may lead to the development of products which may be licensed to FloSure Technologies, of which I am a consultant. This research has been managed to eliminate any potential conflicts arising from this arrangement.

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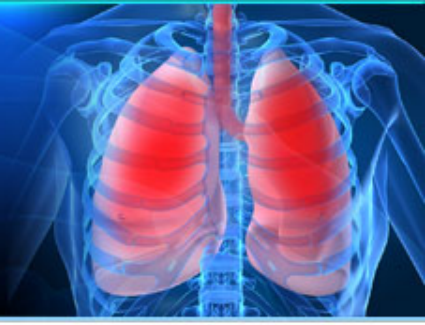
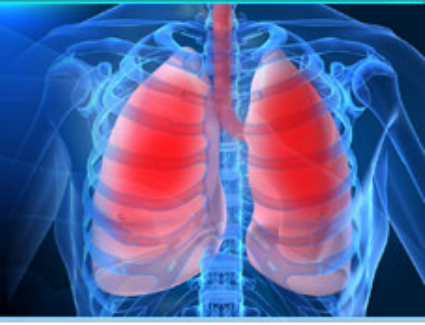
Objectives



- Learning Objectives For This Presentation
  - Review Ventilator Acquired Pneumonia Strategies
  - Discuss Optimization of Tracheostomy Cuff Pressures
  - Analyze Subglottic Suction Port Design
  - Discuss Clinical Experiences
  - Report Findings of Randomized Control Trial

Clinical Background

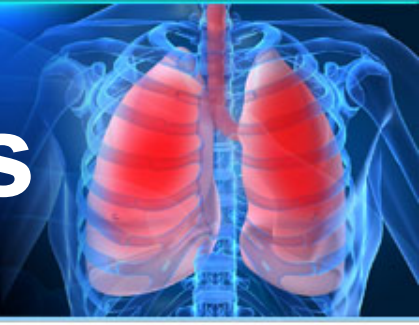


- VAP rates in our 40 bed ventilator unit at Eastchester Rehabilitation & Healthcare Center averaged 12.5 – 20%
- Transfer rates to hospital averaged 50%
- Mortality rate for transferred patients averaged 50%
- Cost per incident $5K

Clinical Background – cont.

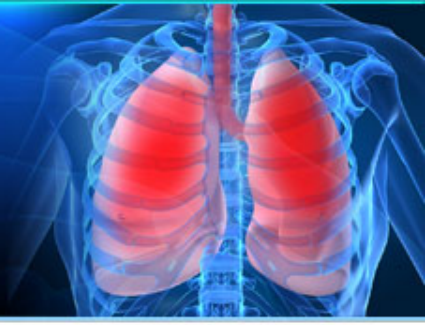
- VAP rates are top priority in unit
  - Increased duration on mechanical ventilation
  - Quality assurance – index of quality care
  - Feeder hospitals are evaluating contracts based on VAP rates and 30 day readmission rates

VAP Prevention Strategies



- Main goal is decreasing rate of bacterial contamination and colonization of oropharynx and lower respiratory tract
- Airway protection – decreasing risk of micro-aspiration of contaminated secretions around tracheostomy cuff.
- Implement new respiratory clinical practice guidelines and new preventive technologies

5 Step VAP Protocol

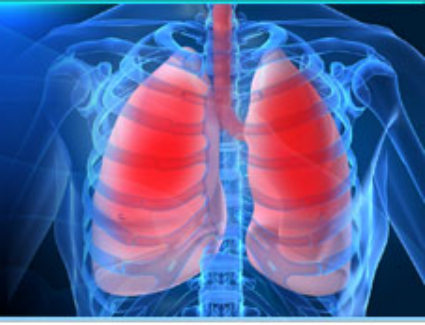


- Head of bed 30-45 degrees
- DVT prophylaxis
- Proton pump inhibitor
- Chlorohexidine 0.12% oral rinse
- Daily weaning from mechanical ventilation

5 Step VAP Protocol - cont.

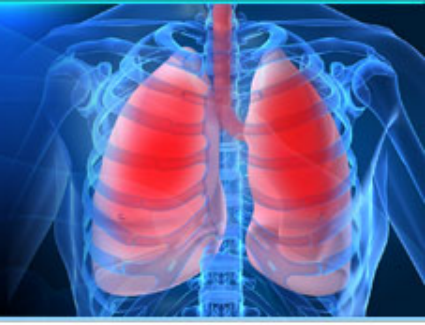
- This protocol was implemented in September 2014
- Analysis of data showed no significant impact on average VAP rate of 16.25%
- We determined that we needed to evaluate and implement new preventive technologies

Subglottic Tracheostomy Tubes



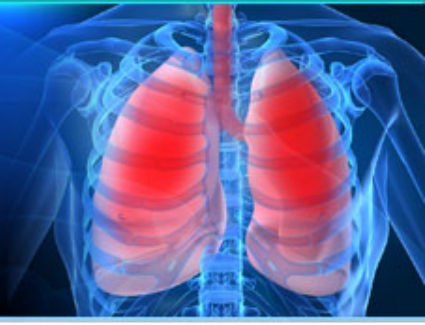
- September 2014 – switch all 40 patients to subglottic tracheostomy tube
- Anticipate VAP rates to decrease due to promise of removal of secretions from subglottic space
- Resulted in being labor intensive for Respiratory Therapists

Subglottic Tracheostomy Tubes - cont.



- Each subglottic port had to be manually aspirated using a 20cc syringe
- Performed 4x/shift
- Presented many challenges:
  - Difficult to apply consistent & safe suction pressures
  - Ensuring maximal aspiration of subglottic volume

Subglottic Tracheostomy Tubes – cont.

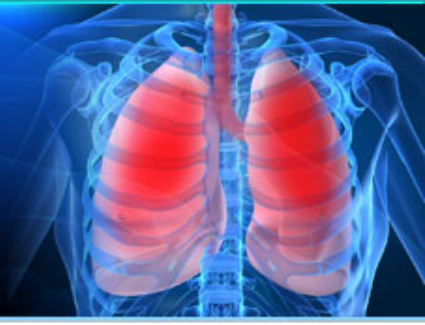


- Patient comfort level
- Tracheal tissue damage – often blood tinged
- Risk of nosocomial infections

Maximum Pressure (mmHg) Generated by Syringe

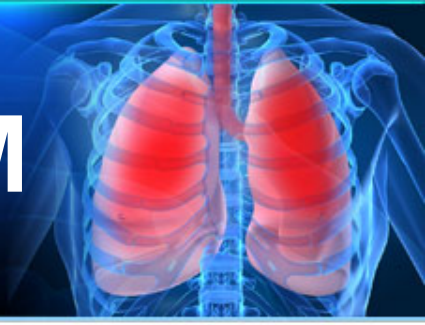
20 cc Syringe generates -706 mmHg pressure which is well over over 4 times the AARC Recommended Pressure Guideline of -150 mmHg for Intermittent Subglottic Aspiration

Subglottic Tracheostomy Tubes – cont.



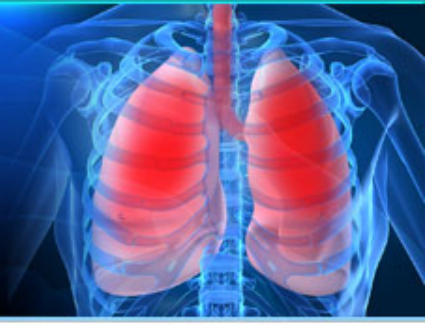
- Therapists reported subglottic ports would often clog
- Require saline lavages which would further increase risk of VAP
- Addition of subglottic tracheostomy tubes resulted in no change to VAP rate over 5 month evaluation period

Introduction of SIMEX cuff M



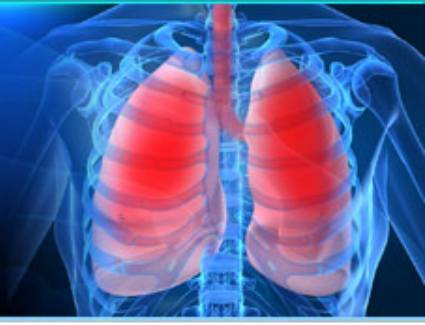
- March 2015 – instituted trial of 5 SIMEX cuff M devices
- Initial settings: -100 mmHg/10 second duration/10 minute intervals
- Adjusted settings based on 3 factors:
  - Aspirate volume
  - Patient comfort level
  - Evidence of tracheal tissue trauma

Introduction of SIMEX cuff M – cont.



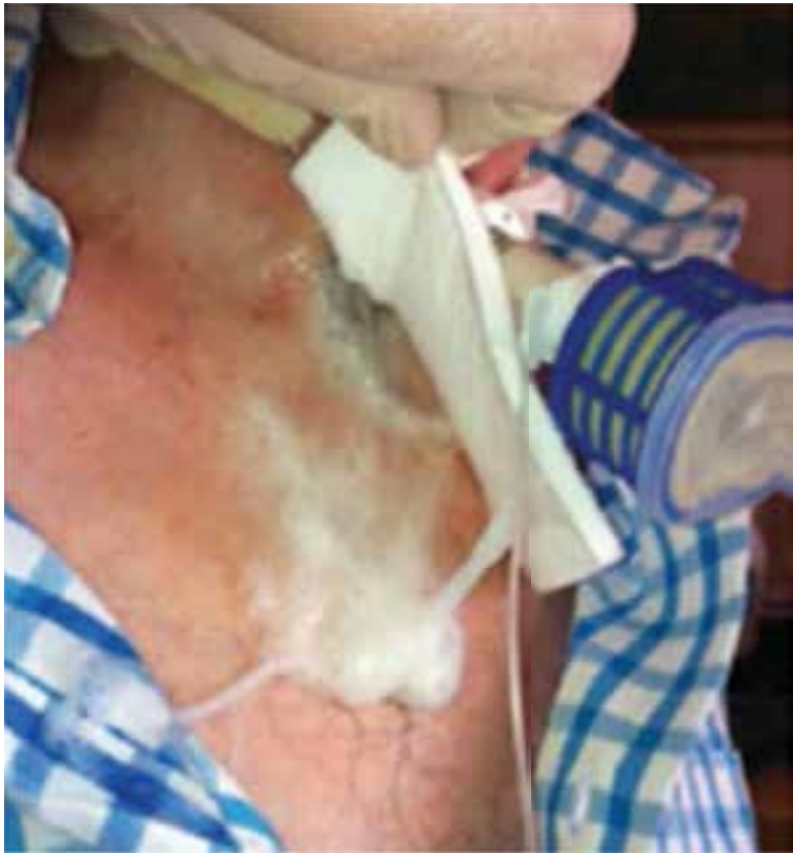
- Trialed 5 devices for 8 months – 10 patients
- Determined optimal suction settings:
  - -150 mmHg/12 second duration/10 minute intervals
  - Suction collection averaged 60-120ml/day
  - Significantly reduced Therapist time at bedside

Observations

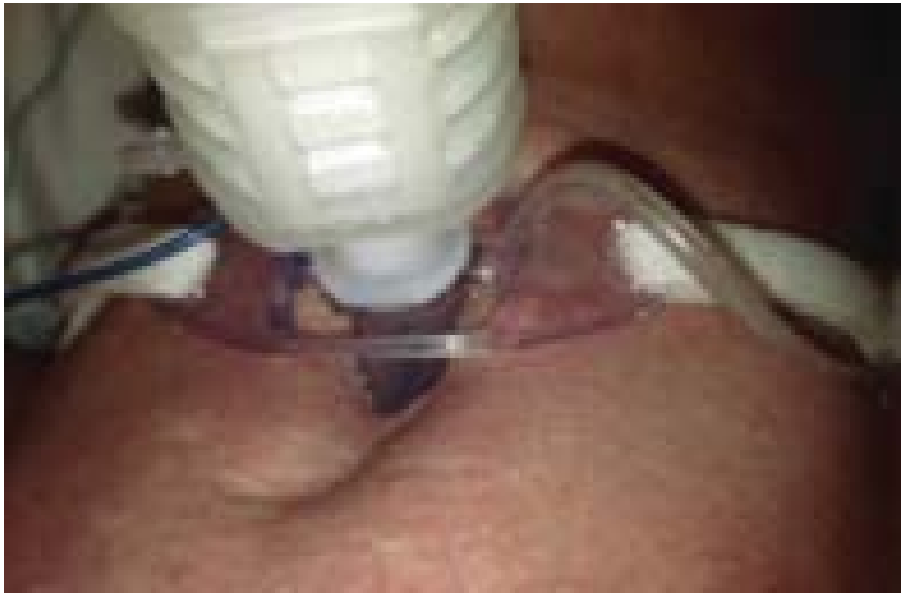


- Maceration of tissue surrounding stoma decreased significantly
- Decreased need to frequently change soiled tracheostomy ties
- Decrease in soiling of surrounding clothes
- Patients reported no tracheal discomfort

Observations – cont.

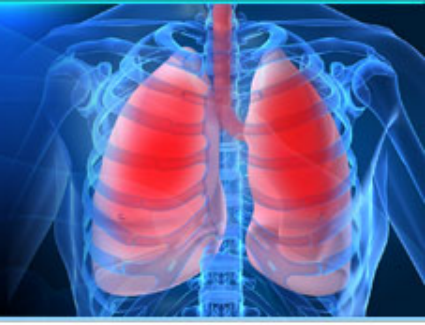


Example of overflow of secretion from the stoma and soiling of garments and linens when syringe or general purpose suction pump is used for aspiration.



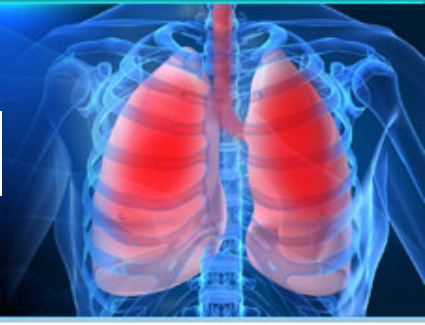
Example of how the patient's stoma looks using the SIMEX cuff M Subglottic Aspiration System. There is no overflow of secretion resulting in no maceration and no cross contamination.

Results of Initial Trial



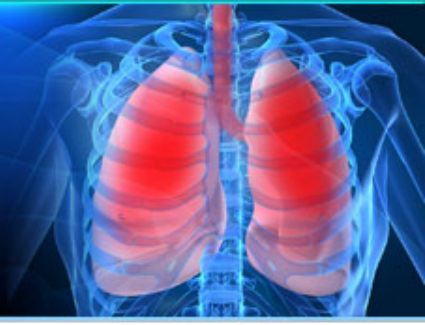
- At conclusion of 8 month – 10 patient trial – no VAP development in these patients
- Results significant enough to warrant further study

Randomized Control Trial



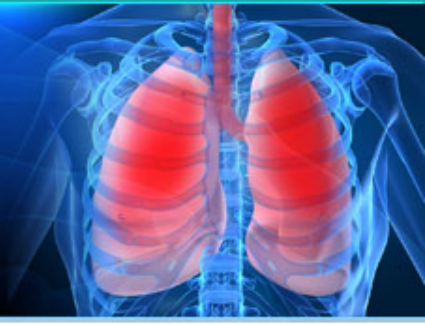
- Represented first of its type for automated subglottic aspiration systems in the world
- November 2015 – began 40 patient IRB approved RCT of SIMEX cuff M
- 25 patients on device – 15 control group
- VAP 5 Step Protocol instituted on all patients

Subglottic Tracheostomy Design



- After introduction of the automated subglottic aspiration system – focus attention on tracheostomy tube
- Therapists noted that patient positioning played a role in suction volume

Subglottic Tracheostomy Design – cont.

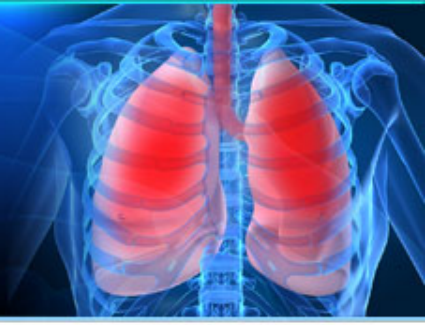


- Semi-Fowler's position (30-45^0) – consistent subglottic secretion volumes
- Full or high Fowler's (90^0) – inconsistent or no volume
- Many high-functioning rehabilitation patients are in wheelchairs or geri chairs – 70^0 - 90^0

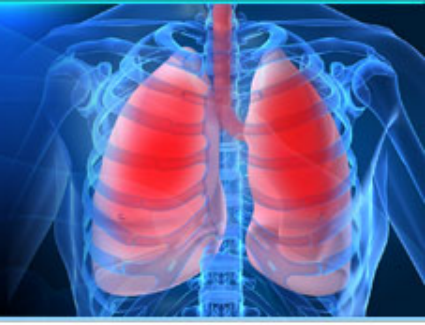
Subglottic Port Positioning

- Most tracheostomy tubes to date have small posterior or lateral-posterior subglottic ports
- Efficient in supine to semi-Fowler positions (0-45^{o})
- Issue – many patients on our unit are at 70-90^{0} positions

Animation Video



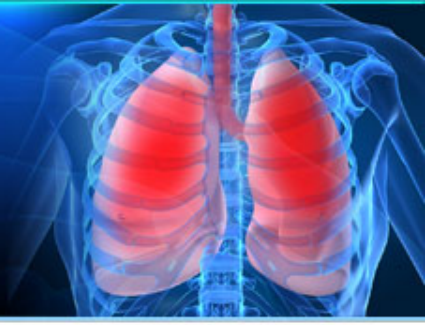
Port Positioning



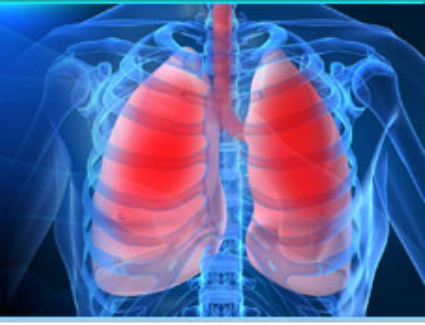
- Subglottic port positioning is too high above cuff
- Transverse internal diameters of trachea average 20mm in men and 15.5mm in women
- Approximately 5-8ml of subglottic secretions can accumulate and pool between tracheostomy cuff and suction port

Port Positioning – cont.

Animation Video

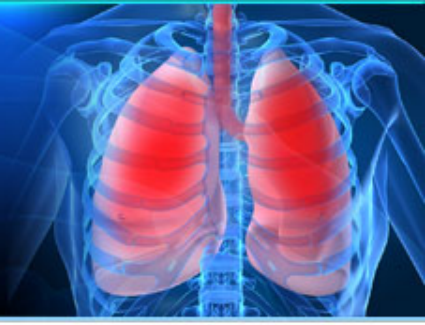


Subglottic Tracheostomy Cuff Pressures



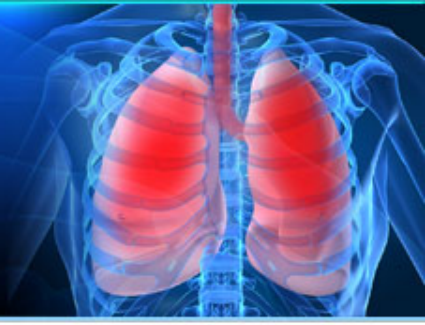
- Respiratory Therapists set cuff pressures to ‘minimal occluded volume’ (MOV) – 18 – 25 cmH_20
- These pressures set to prevent:
  - Lymphatic flow obstruction (edema)
  - Venous flow obstruction (congestion)
  - Decreased venous-capillary blood flow (ischemia)

Subglottic Tracheostomy Cuff Pressures – cont.



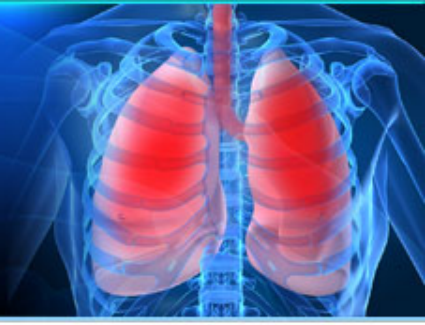
- Our research has determined that MOV pressures are too low to prevent secretions from leaking around cuff.
- Cuff pressures between 25 – 35 cmH_2O were more ideal
- Results are similar to Chendrasehkar, et al (2013) – concluded ETT cuff pressures of 29.5 cmH_2O ($\pm$ 3.2 cmH_2O) were ideal to prevent leakage around cuff

Subglottic Tracheostomy Cuff Pressures – cont.



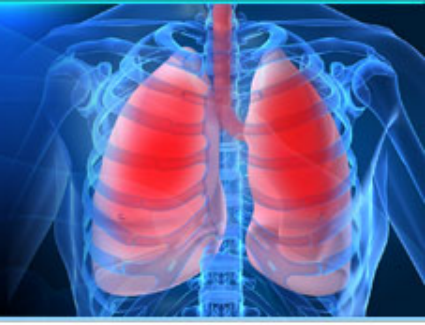
- Current recommendations of MOV (18 – 25 cmH2O) inherently expose patients to higher risk of VAP
- We propose implementing cuff pressures that are clinically ideal verse setting to standard numbers
- Each patient's ideal cuff pressure will vary

Subglottic Tracheostomy Cuff Pressures – cont.



- In 25 subject SIMEX cuff M group – increased cuff pressures adequately sealed airway
- Instituted new protocol to maintain cuff pressures between 25 – 35 cmH2O
- Result – as cuff pressures increased – amount of subglottic volume also increased

Subglottic Tracheostomy Cuff Pressures – cont.

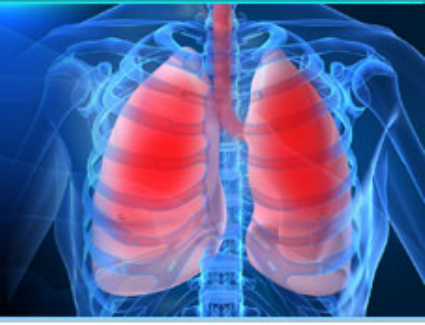


Optimal Suction Settings on SIMEX cuff M Device	
-150 mmHg – 12 second duration – 10 minute intervals	
Cuff Pressures	Subglottic Suction Volume
18 – 25 cmH2O	60 – 120 ml/day
25 – 30 cmH2O	130 – 250 ml/day
30 – 35 cmH2O	250 – 420 ml/day

Evidence of significant secretion leakage around tracheal cuff at lower cuff pressures

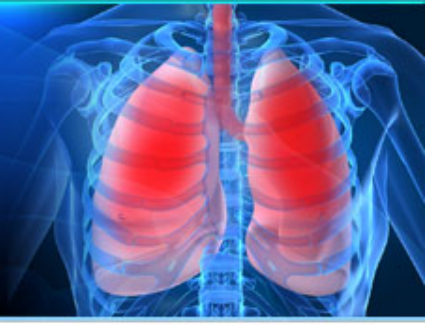
"sweet spot" for optimal cuff pressure and secretion removal is 30 – 35 cmH_2O

Subglottic Tracheostomy Cuff Pressures – cont.



- Bronchoscopy and tracheoscopy were performed by a pulmonologist and ENT on each patient on SIMEX device
- Revealed no tracheal wall ischemia, congestion, or edema
- No patient discomfort
- No incidences of patient difficulty swallowing solid foods due to decrease in esophageal diameter

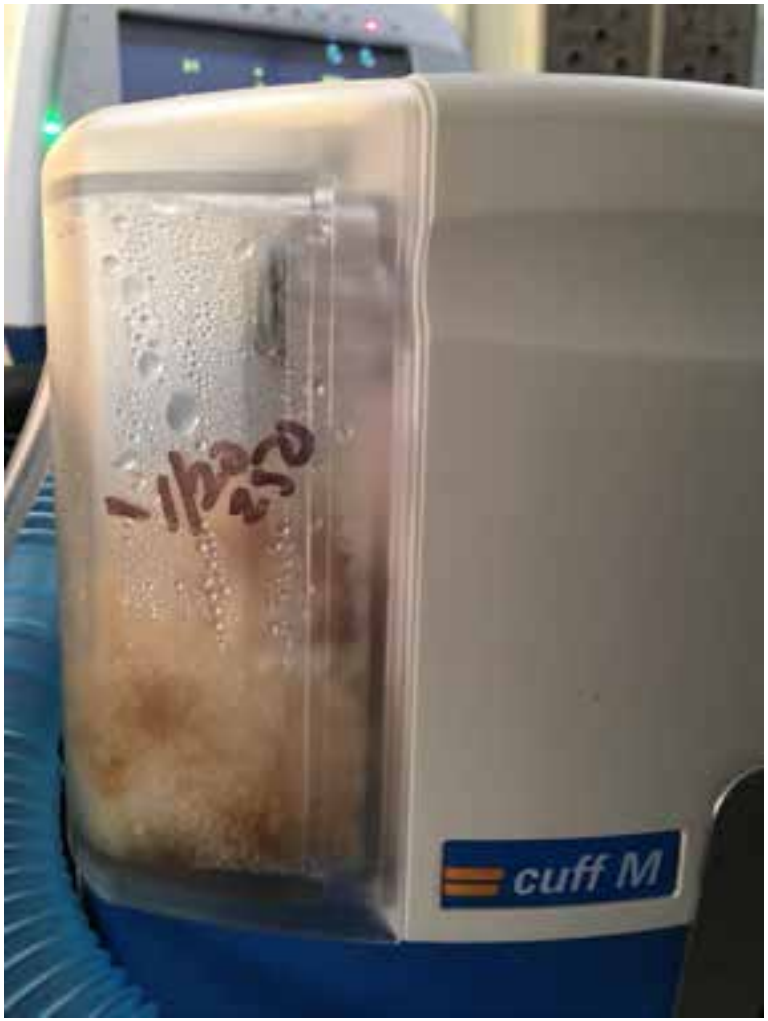
SIMEX cuff M Device



- Therapists report easy to implement and monitor
- Canisters are 250ml and self-contained with gel component
- Device notifies when suction canister is full

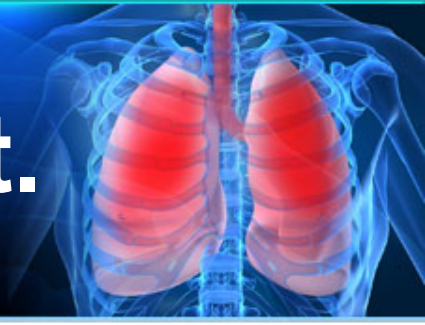
SIMEX cuff M Device – cont.

Example of SIMEX cuff M Device installed at Patient's bedside



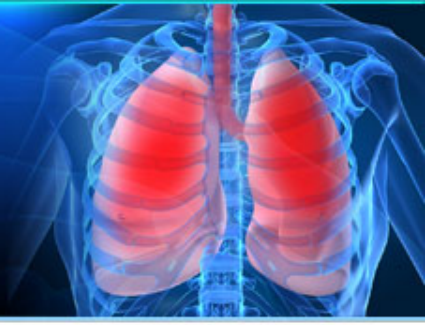
Example of volume of secretions collected in the collection canister

SIMEX cuff M Device – cont.



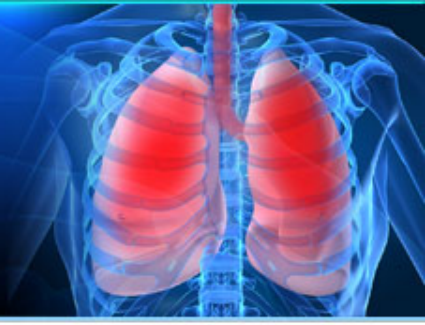
- Decreases labor intensive manual aspiration of subglottic port
- Decreases the clogging of the subglottic port and eliminates need for saline lavage to maintain patency
- Reduces RT time spent at bedside maintaining subglottic tracheostomy

RCT Conclusions
4 Month Study



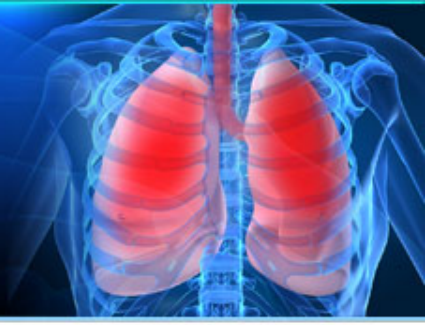
- VAP rate of 8% (2 subjects) in 25 subject SIMEX cuff M group.
- VAP rate of 33% (5 patients) in 15 subject control group
- Findings indicate a dramatic reduction of VAP incidences among long-term mechanically ventilated patients in conjunction with 5 Step VAP Protocol

RCT Conclusions
4 Month Study – cont.



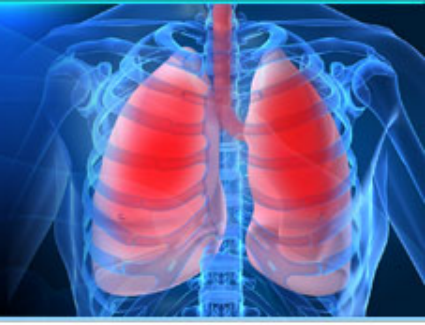
- No Adverse Effects:
  - Tracheal wall trauma
  - Patient complaints
  - Patient discomfort or inability to tolerate

Post RCT



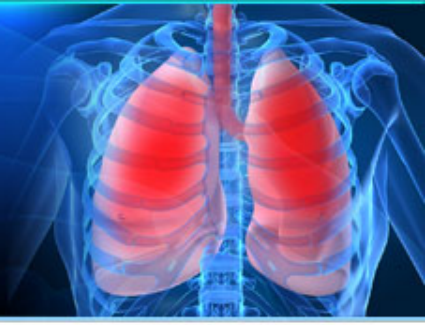
- Currently have expanded long-term ventilator unit to 80 beds
- 6 bed phrenic nerve pacing unit
- 6 bed LVAD unit

Post RCT – cont.



- 40 patients on SIMEX cuff M automated subglottic aspiration system
- In last 8 months – 2 confirmed VAP – 1 treated in-house
- 1 patient required transfer to hospital and returned within 7 days

Post RCT – cont.



- Saved significant facility resources and keeps patients in beds – increasing revenue
- Decreased 30 day transfer rates back to feeder hospitals – improving relationships
- Decreased time spent on mechanical ventilation averaged 5 days and improved quality of life.